REMARKS

Claims 1-8 are all the claims pending in the application.

A. Response to Claim Rejections under 35 U.S.C. § 112, 1st Paragraph

On page 2 of the Action, claims 2-3 and 5-7 are rejected under 35 U.S.C.§ 112, first paragraph, because the Examiner alleges that the specification, while being enabling for a limited number of compounds of the formula, does not reasonably provide enablement for all of the possible structures claimed.

The Examiner further alleges that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to *make and use* the invention commensurate in scope with these claims. For instance, the Examiner states that with respect to the *making* aspect of the invention, of the multiple possibilities for R^1 and R^2 and R^3 and p and Q groups in claim 5 and several substituents in claim 6, the specification is enabling for the making of one possibility. Likewise, in support of the biological activity of the claimed compounds (i.e., *potential* utility), the Examiner asserts that the disclosure is limited to describing only the single possibility of a single compound with specific substituents linked to the treatment of hot flashes.

Applicants first note that at page 3 of the Action, the Examiner refers to the "compounds of the formula" as the elected group, however, Applicants submit that the elected group is drawn to "a method" and not "compounds."

Regarding the merits of the rejection, Applicants respectfully traverse.

Applicants submit that the PTO bears the initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the

application; this includes, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. See also MPEP § 2164.01 and § 2164.04.

The Examiner has not met her burden of providing a reasonable basis to question the enablement provided for the claimed invention. For example, Applicants point out that, contrary to the Examiner's assertions, the original specification teaches compounds of formula (I) (which is the formula recited in claim 7), can be prepared by known methods as described in the literature references mentioned at page 40, lines 23-25 and page 41, line 1 of the specification. Further, at pages 33 and 39-41, specific examples of compounds of formula (I) other than (Ib) (which is the formula recited in claim 6) are described. Additionally, the working examples show synthesis of compounds within the scope of formula (I) recited in claim 7. For example, Example 1 tests compounds within the scope of claim 7 and describes an assay for determining the activity of the compounds. Thus, the specification as filed provides sufficient guidance such that one of ordinary skill in the art could make and use the compounds of the claims and practice the full scope of the invention without undue experimentation.

Moreover, Applicants are not limited by the examples in the specification. So even if there is only one representative compound of formula (Ib) in the specification, the claimed compounds would be enabled as long as one of ordinary skill in the art would be able to make and use other compounds within the scope of the claims based on the description that is provided in the specification and knowledge and skill available in the art.

Further, the Examiner's statement that only one compound within the scope of formula (Ib) is synthesized is not the proper test. A specification may be enabling without any working examples. See MPEP 2164.02. In this regard Applicants have pointed out examples of the

claimed compounds in the specification and, therefore, there is ample guidance for one skilled in the relevant art to make and/or use the claimed invention without undue experimentation.

Applicants also point out that Applicants' burden under 35 U.S.C. §112, first paragraph, is not to demonstrate that the instant compounds with all other possible substituents will retain the same properties, but to provide an enabling disclosure which teaches one skilled in the art to make and use the scope of the claimed invention without undue experimentation. Thus, even if the claims encompass inoperative species, the claims comply with the enablement requirement as long as undue experimentation is not necessary to determine which species would or would not work.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph rejection of claims 2-3 and 5-7.

B. Response to Claim Rejection under 35 U.S.C. § 112, 2nd Paragraph

On page 6 of the Action, claims 2-3 and 5-7 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Specifically, claims 2-3 and 5-7 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite regarding as to the "effective amount" of the non-peptidic compound having gonadotropin releasing hormone activity.

Applicants traverse the rejection.

The Examiner's focus in determining whether the claims are definite in compliance with 35 U.S.C. § 112, second paragraph, should be whether the claims set out the claimed subject matter with a reasonable degree of clarity and particularity in light of (1) the content of the specification; (2) the teachings of the prior art; and (3) the claim interpretation that would be

given by one of ordinary skill in the art. In this regard, the specification clearly provides that the daily dose varies depending on severity of symptom; the age, sex and weight of the subject to be administered; a time and an interval of administration, the nature, composition and kind of pharmaceutical preparation; and the kind of active ingredient. Additionally, the specification teaches that when orally administered for treating hot flashes, a daily dose is usually 0.1 to 300 mg, and further preferably about 10 to 200 mg for an adult and is usually administered in 1 to 4 divided doses. (See Specification pages 79-80). Moreover, "an effective amount" is a fairly common term in pharmaceutical patents and one of ordinary skill in the art would know what is meant by this term. Thus, in view of the teachings in the specification and the claim interpretation given by those of ordinary skill in the art, the meaning and scope of the claim language is readily ascertainable.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph, rejection of claims 2-3 and 5-7.

B. Response to Claim Rejections under 35 U.S.C. § 103

On pages 7-13 of the Action, claims 2-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being obvious over Furuya et al. (US 6,297,379), hereinafter '379, Furuya et al. (US 6,048,863), hereinafter '863, , and Furuya et al. (US 6,187,788), hereinafter '788 each in view of Takayoshi et al. (Brain Research, 754 (1997) 88-94.

Applicants respectfully traverse. Specifically, Applicants submit that the Examiner has not made a prima facie showing of obviousness.

The Examiner's position is based on the assertion that hot flashes is a sex hormone-dependent condition because estrogen is involved. However, Applicants submit that the question is not whether hot flash is considered a sex hormone-dependent condition, but whether, based on

the teachings in the prior art, one of ordinary skill in the art would have been motivated to modify or combine the references with a reasonable expectation of success.

In this regard, Applicants submit that even if hot flashes could be considered as a sex hormone-dependent condition (a point Applicants do not concede) it does not mean that one of ordinary skill in the art would have had a reasonable expectation of success in treating hot flashes by administering the compounds taught by Furuya et al as suggested by the Examiner.

As Applicants have pointed out, the Furuya et al references teach that the disclosed compounds are useful for preventing and/or treating sex hormone-dependent cancers, prostatic hypertrophy, hysteromyoma, endometriosis, precocious puberty, amenorrhea, premenstrual syndrome, multiocular ovary syndrome and acne, which are conditions that are caused, exaggerated or maintained by sex hormones. In other words, the conditions taught by the Furuya et al references are conditions where sex hormones are increased.

To the contrary, Applicants have argued that hot flashes occur under conditions where sex hormone levels are lowered, which is the opposite effect from the conditions taught by Furuya et al.

Thus, one of ordinary skill in the art would not have had a reasonable expectation of success of treating a condition which occurs where sex hormone levels are lowered by administering an agent shown to be effective in conditions where sex hormones are increased. Accordingly, it would have been expected that there would be a possibility that the thienopyridine derivative of the present invention causes, rather than treats, hot flashes because such a derivative is known to have GnRH antagonizing activity, i.e., sex hormone level lowering-activity.

Further, although Takayoshi relates to hot flashes, it does not remedy the deficiencies of Furuya et al. The Examiner asserts that Takayoshi teaches gonadotropin-releasing hormone antagonism and its relation with treatment of hot flashes with such agents. However, Takayoshi tests the effects of administering GnRH and Antide, an antagonist of GnRH, on thermoregulatory skin vasomotion. The Antide compound used in Takayoshi is of a different formula from the instantly claimed compound and is not structurally related to the claimed compounds. Applicants point out that a reference must be considered for all that it teaches or reasonably suggests to those of ordinary skill in the art and, in its proper context, Takayoshi teaches the treatment of hot flashes with a specific compound, i.e., Antide, but does not teach the treatment of hot flashes with the presently claimed compound or with a compound that is structurally related to the claimed compounds.

Thus, Applicants submit that based on the large number of known GnRH antagonists, one of ordinary skill in the art would not have had a reasonable expectation of success to select and use the presently claimed compound to treat hot flashes based on the teachings of the cited references. None of the Furuya et al references teaches the use of thiophene compounds in treating hot flashes and Takayoshi does not teach the use of the presently claimed compound or a structurally related compound in treating hot flashes.

In view thereof, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection of claims 2-3 and 5-7.

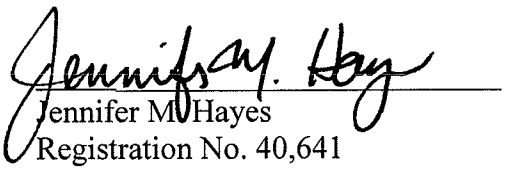
C. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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Date: May 26, 2009